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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,561	10/06/2003	Usha Kasid	224381	5256

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,561	KASID ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *13-22 and 25-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5-31-05; 2/9/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 6-26-06.

Claims 1-31 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 6-26-06 is acknowledged. The traversal is on the ground(s) that the different Groups have a disclosed relationship to each other (e.g. that the polypeptides, nucleic acids, antibodies, epitopes, and the various methods of modulation, treatment and/or diagnostics all relate to the polypeptide of SEQ ID No. 2, encoded by SEQ ID NO. 1) and therefore do not represent independent inventions. Applicants also argue that examination of all of the various Groups would not pose a serious burden on the examiner. This is not found persuasive because the polypeptides, polynucleotides, antibodies, epitopes, methods of treatment, modulation and diagnosis are different and distinct and are properly restricted. The claims of Group I, for instance, are drawn to polynucleotides and antisense, while the claims of Group II are drawn to polypeptides. The data bases required for a proper search of the polynucleotides claimed would not be coextensive with the proper search required of the data bases relating to the chemically distinct proteins of Group II, whether or not the language of the claims draws a general relationship between nucleic acids, proteins, antibodies, epitopes, methods of diagnosis, treatment or modulation. And, contrary to Applicant's assertions, the proper

searches required for examination of all of the Groups claimed would pose a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-22, 25-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4-21-06.

Claim Objections

Claim 4 is objected to because of the following informalities: This claim has two periods. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the polynucleotides claimed cannot be determined because the recitation of a polynucleotide encoding amino acids from about 1 to about 529, or an isolated nucleic acid from about 2 to about 2468 (e.g. and subsequences thereof as claimed) is indefinite. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 8-12 , 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions comprising polynucleotides that are at least 90% identical to a polynucleotide encoding SEQ ID NO. 2, polynucleotides encoding polypeptides with at least one conservative amino acid substitution of SEQ ID NO. 2, and antisense to "BRCC-3", with no nucleic acid sequence specified for "BRCC-3.". The specification, claims and the art do not adequately describe the distinguishing features or attributes concisely shared by the members of this broad genus of nucleic acids. The specification discloses SEQ ID No. 1, encoding SEQ ID NO. 2. The genus of nucleic acids claimed encompasses a myriad of structures (*e.g.* thousands of nucleic acid sequences are included among those encoding for "conservative amino acid substitutions" of SEQ ID NO. 2, or those encompassed by polynucleotides sharing 90% homology with SEQ ID No. 1, or encoding SEQ ID NO. 2) and the specification and claims do not adequately teach a representative number of species for the broad genus

claimed (*e.g.* a single species of BRCC-2 does not provide adequate description for the broadly claimed species of target genes embraced by claims 23 and 24).

Concise structural features that could distinguish structures within the genus from others are missing from the disclosure. No common structural attributes identify the members of the claimed genus, and distinguish members within the claimed genus from those outside of it. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Gokhale et al.

Gokhale et al (Acc. No. AF303178, see accompanying sequence alignment data) teach a polynucleotide encoding SEQ ID NO. 2, and polynucleotide subsequences thereof (see *Novel Transcript in Human Breast Cancer Cells*, Acc. No. AF303178, accompanying sequence alignment data).

Claims 1, 3-7 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Ota et al.

Ota et al (EP 1074617) teach a polynucleotide encoding amino acids 2-259 of SEQ ID NO. 2, polynucleotide subsequences thereof, and antisense oligonucleotides thereof (see accompanying alignment with Acc. No. AX878198 of EP 1074617. This reference contains over 6000 pages and so has not been included. A full copy of the reference will be provided upon request by Applicant.).

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al.

Williams et al (WO/9958675) teach polynucleotides comprising between 2-2468 contiguous nucleotides of SEQ ID NO. 1, or encoding from about 1 to about 529 amino acids of SEQ ID NO. 2 (see Acc. No. AAA00789 and the accompanying sequence alignment data).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form

the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schlegel et al.

Schlegel et al (WO200142467) teach an antisense that targets SEQ ID No. 1 (BRCC-3). (see Acc. No. AAH68866 and the accompanying sequence alignment data). The burden of establishing whether the prior art oligonucleotide has the function of inhibiting gene expression as claimed falls to applicant. See (In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977): "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product... Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced b the PTO's inability to manufacture products

or to obtain and compare prior art products [footnote omitted]. See also MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing In re Fitzgerald 205 USPQ 594, 596 (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, absent evidence to the contrary, since the oligonucleotide disclosed by Schlegel et al meet all of the structural limitations of the instantly claimed invention, it would necessarily be presumed to have the functionality claimed, of inhibiting expression of BRCC-3.

Therefore, absent evidence to the contrary, claim 23 is anticipated by or, in the alternative, obvious over Schlegel et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gokhale et al as applied to claims 1-7 above, and further in view of Huang.

Gokhale et al is relied upon as set forth in the 102(a) above.

Gokhale et al do not teach methods of transforming a recombinant host cell comprising transforming it with a recombinant vector comprising the polynucleotide of claim 1, nor methods of producing a recombinant polypeptide, nor liposomal formulations comprising an antisense that inhibits the expression of a known target gene.

Huang (USPN 5,811,304) teaches recombinant vectors in recombinant host cells for the expression of recombinant proteins in vitro. Huang also teaches antisense for the inhibition of target gene expression of a known target gene, and liposomal formulations for delivery of nucleic acids to host cells in vitro (see esp. col. 18, 20, claims 9 and 10).

It would have been obvious to one of skill in the art to insert the polynucleotide sequence of SEQ ID NO. 1 into an appropriate recombinant expression vector and transfect or transform a host cell in vitro with the expression construct comprising SEQ ID NO. 1 and generate recombinant polypeptide encoded by SEQ ID No. 1 because the polynucleotide had been disclosed previously by Gokhale et al and it was routine experimentation in the art at the time the invention was made to subclone

polynucleotides into expression vectors, transfect host cells in vitro and express recombinant polypeptides. One of skill in the art would have been motivated to express SEQ ID NO. 1 because it expresses a product that has been associated with breast cancer, as taught previously by Gokhale et al and one would have been motivated to study the cellular localization, expression patterns and biological activities of this expression product and compare its expression in various neoplastic states in order to study its role in the cell and in the neoplastic process. It would have been obvious to one of ordinary skill in the art to design and test antisense that specifically target SEQ ID NO. 1 because the design and use of antisense for target gene inhibition in vitro was routine at the time the invention was made, as taught previously by many in the art, including Huang. One would have been motivated to inhibit target gene expression of SEQ ID NO. 1 to study the effects of its inhibition on cellular processes and one of ordinary skill in the art would have expected that antisense would lead to inhibition of expression of the target gene in vitro. One would have been motivated to introduce antisense into target cells in vitro using liposomal compositions because it was well known at the time the invention was made that liposomal compositions enhance target cell delivery of antisense in vitro. One of ordinary skill in the art would have expected that liposomal compositions would enhance cellular uptake of antisense oligonucleotides. For these reasons the instant invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
9-11-06